Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2019, 8 (4): 1870-1879

(International Peer Reviewed Journal)

Advancement and Validation of an Innovative Stability Indicating RP-HPLC Assay Method of Rivaroxaban in Tablet Formulation

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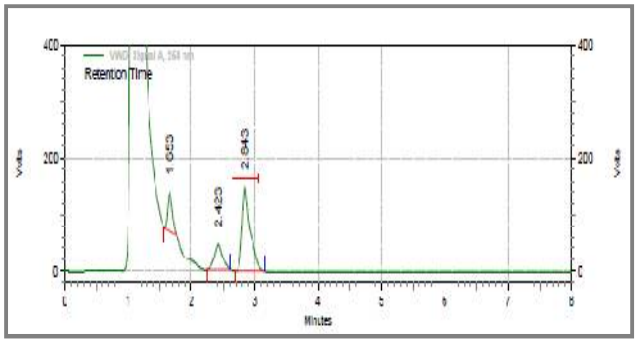
Accepted on 3rd June, 2019

ABSTRACT

An innovative RP-HPLC assay procedure has been established for rivaroxaban in pharmaceutical dosage forms. Outstanding segregation of the rivaroxaban was accomplished on Thermo BDS, C8, 150 x 4.6, 5µm column using the mobile phase (potassium dihydrogen phosphate buffer (pH 2.5±0.05) and acetonitrile in the ratio of 50:50 %v/v) at a flow rate of 1.0ml/min with UV detection of 254nm in ambient temperature. The recommended RP-HPLC procedure had viably separated rivaroxaban from its degradation products, making it stability-indicating. A calibration graph was obtained over six different concentrations in the range of 8.0-48 µg mL^{-1} illustrating regression equation of y=1103652.16x-10146 (r^2= 0.9999) for rivaroxaban admitting a superb relationship. Reasonableness of this system for the quantitative determination of the rivaroxaban was demonstrated by validation as per the prerequisites of International Conference on Harmonization (ICH) guidelines.

Graphical Abstract



Chromatogram of rivaroxaban in peroxide degradation.

Keywords: Rivaroxaban, Stability Indicating, Method Validation, HPLC Estimation.